Bakery Products

FDA Alerts Consumers That Certain Healthy Way Brand Sprouted Grain Bread Products May Contain Stone Pieces

Dozens of Injuries Reported From Stone Pieces Found in Grain Bread

On August 9, 2004, FDA issued a warning to consumers based on reports from the Canadian Food Inspection Agency that certain Healthy Way brand name sprouted grain bread products may contain small pieces of stone that could cause injuries. The products were manufactured by Olafson's Baking Company of Annacis Island, British Columbia, Canada, and were distributed through retail outlets in the states of Washington and Oregon.

Dozens of injuries were reported throughout Canada -- mostly involving tooth damage.

The following Healthy Way brand sprouted grain bread products were affected by this alert: Grain and Seed (21 ounce); Twenty Grain (21 ounce and 2 Pack); Flax Loaf (21 ounce); Sprouted 100% Whole Wheat Bread (21 ounce); Carb Conscious (16 ounce); and Alpine (21 ounce).

Warning Letter Issued to Facility for Adulterated and Misbranded Products

FDA's San Juan District Office issued a Warning Letter on September 14, 2004, to E. Franco & Co., Mayaguez, Puerto Rico. An FDA inspection of the facility on April 19-22, 2004, found violations of the Federal Food, Drug, and Cosmetic Act (the Act) for pastry products and Guava Filled Rolls (Brazo Gitiano con Guayaba). These violations caused the products to be adulterated and misbranded.

The warning letter cited the firm for a number of significant insanitary conditions present at the facilities at the time of the inspection. These conditions caused products manufactured in the facility to be adulterated under section 402(a)(4) of the Act in that they have been prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth, or may have been rendered injurious to health. Objectionable conditions observed include the following:

- Failure to exclude pests from the food plant (21 CFR 110.35(c));

- Failure to hold foods that support the growth of undesirable microorganisms in a manner that prevents the foods from becoming adulterated (21 CFR 110.80(b)(3));

- Failure to store and dispose of rubbish to minimize the potential for waste becoming an attractant and harborage or breeding place for pests (21 CFR 110.37(f)); and

- Failure to provide adequate screening or other protection against pests (21 CFR 110.20(b)(7)).

The warning letter also cited the firm for failing to declare the presence of color additives and other ingredients.

Warning Letter for Deviations from the Current Good Manufacturing Practice Regulation

FDA's Baltimore District Office issued a Warning Letter on June 28, 2004 to Marty's Italian Bakery, Mt. Claire, West Virginia. An FDA inspection on February 26, March 1st and 3rd determined that the firm had serious deviation from the Current Good Manufacturing Practices regulation. Based on the inspection, the firm's various baked bread products were considered adulterated within the meaning of 402(a)(4) of the Federal Food, Drug, and Cosmetic Act due to the firm's failure to exclude pests from the processing area (21 CFR 110.35(c), failure to maintain equipment to facilitate cleaning (21 CFR 110.40(a)), failure to conduct cleaning and sanitizing operations (21 CFR 110.35(a), and failure to store trash in an adequate manner (21 CFR 110.37(d)(1)). Additionally, a variety of the firm's baked bread products were misbranded under section 403(q) of the Federal Food, Drug, and Cosmetic Act due to the labels failing to bear nutritional statements.

Beverages

Warning Letter Issued to Tea Manufacturing Plant for Unsafe Food Ingredients

FDA's Seattle District Office issued a Warning Letter on January 14, 2004, to Herbal Junction, Eugene, Oregon. An FDA review of the labels for the product "Livertea and Justice Herbal Enzyme Elixer Tea" showed that the product was represented for use as a conventional food and that the product violated the Federal Food, Drug, and Cosmetic Act.

Under the Act, any substance intentionally added to a conventional food must be used in accordance with a food additive regulation, unless the substance is the subject of a prior sanction, or is generally recognized as safe (GRAS) among qualified experts for its intended use in foods. According to its label, the "Livertea and Justice Herbal Enzyme Elixer Tea" contained una de gato, peony, ho shou wu, muira pauma, chanca peidra, jatoba, and catuaba. FDA was not aware of any basis to conclude that these ingredients were the subject of a prior sanction or are GRAS for use in tea products. Nor were these substances used in accordance with a food additive regulation. Thus, the food containing these substances was adulterated under section 402(a)(2)(C) of the Act (21 U.S.C. 342(a)(2)(C)) and could not be legally marketed in the U.S.

Warning Letter for Deviations from Juice HACCP Regulations

FDA Inspection Reveals Firm Has No Written Juice HACCP Plan

FDA's Seattle District Office issued a Warning Letter on October 23, 2003, to Fresh Juice Works, Incorporated, Seattle, Washington. An FDA inspection on April 1, 3, and 23, 2003, was conducted to determine the firm's compliance with FDA's juice processing regulation (21 CFR 120).

FDA determined that the firm produces the following 100% juice products: orange juice; lemon juice; lime juice; cider apple juice; and grapefruit juice. Juice products that are 100% juice are required to be produced consistent with the juice processing regulation.

The inspection identified several shortcomings in the production system that appeared to be deviations from the principles of HACCP and significant requirements of the program. The observations of concern includef the following:

1. The firm has no written hazard analysis for any of the 100% juice products that it produces; and

2. The firm does not have a HACCP plan to control the food safety hazard of pathogens for any of the processes used to make 100% juice products.

Juices that are required to be produced under a HACCP system complying with 21 CFR Part 120, but are not so produced are considered adulterated under section 402(a)(4) of the Act.

Warning Letters for Deviations from Juice HACCP Regulations

- FDA's Seattle District Office issued a Warning Letter on November 12, 2003 to Genesis Juice Cooperative, Eugene, Oregon. An FDA inspection on August 20, 2003 determined the firm had serious violations from the juice HACCP regulations. The firm's juice products were adulterated within the meaning of section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act due to no written HACCP plan for the unpasteurized juices [21 CFR 120.8(a)], and no sanitation control records that document monitoring and corrections [21 CFR 120.6(c)].

- FDA's Seattle District Office issued a Warning Letter on October 21, 2004 to Hood River Juice Co., Hood River, Oregon. An FDA inspection on July 14-15 and 19-20, 2004, determined the firm had serious violations from the juice HACCP regulations. Based on the inspection the firm's juice products were considered adulterated under section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act. The firm failed to take corrective action when verification establishes a need; failed to have records documenting the HACCP system; failed to implement monitoring procedures; failed to monitor conditions and practices during processing; and failed to have sanitation control records that document monitoring of conditions.

- FDA's Denver District Office issued a Warning Letter on August 25, 2004 to Two Brothers Dairy, Hotchkiss, Colorado. During a FDA inspection on April 7, 2004, FDA sampled the firm's finished apple cider and found patulin levels in excess of 50 ppb. The FDA investigation determined that the firm had serious violations

from the Juice HACCP regulation. The firm's juice products were adulterated within the meaning of section 402(a)(1) and 402(a)(4) of the Federal Food, Drug, and Cosmetic Act due to the presence of patulin, a poisonous or deleterious substance, and due to the firm not having a written HACCP plan for the pasteurized juices [21 CFR 120.8(a)] and failing to have sanitation control records [21 CFR 120.6(c)].

- FDA's Cincinnati District Office issued a Warning Letter on August 12, 2004 to Paul's Fruit Market, Inc., Louisville, Kentucky. An FDA inspection on April 29 and 30, 2004 determined that the firm had serious deviations from the juice HACCP regulation. Based on the inspection, the firm's unpasteurized juice products were considered adulterated within the meaning of 402(a)(4) of the Federal Food, Drug, and Cosmetic Act due to no written HACCP plan for firm's unpasteurized juices [21 CFR 120.8(a)] and failing to have sanitation control records [21 CFR 120.6(c)].

Bottled Water

Warning Letter for Deviations from GMPs for Bottled Drinking Water

FDA's San Juan District Office issued a Warning Letter to Water World, San Juan, Puerto Rico, on August 9, 2004. The firm was inspected April 3 and 10, 2003 and again April 5 -9, 2004. The firm's bottled drinking water was misbranded under section 403(i)(1) and adulterated under section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act. The firm failed to comply with the regulations regarding bottled water in 21 CFR Part 129. Specifically, the firm failed to collect and analyze at least once a week bottled drinking water for bacteriological purposes, conduct sanitizing operations to ensure sanitation of product water-contact surfaces and critical areas, test cleaning and sanitizing solutions to assure adequate performance, identify products with a production code, and, label products with an appropriate common or usual name.

Candy and Sweeteners

Fraudulent Substitution Leads to Civil Penalties

FDA's Southwest Import District Office investigation concerning the substitution of a lot of refused Mexican candy resulted in the assessment of civil money penalties in the amount of $1,260 against the Montebello, California importer of record. A second penalty in the amount of $1,260 was also assessed against the most responsible management official of the firm for fraudulent substitution of the refused candy.

The firm official admitted to distributing the refused shipment and offering for export a domestically purchased product similar to that of the product which was detained and ultimately refused admission. Since the firm official had direct culpability for the events which took place by the corporation, Customs and Border Protection (CBP) legal staff concurred with the local Fines, Penalties, and Forfeitures Officer in the issuance of both penalties. This was the first time CBP had taken a fraud action on both a corporation and its owner.

Warning Letter Issued to Candy Manufacturer for "LOW CARB" Claims

"LOW CARB" Product Found to Contain Same Amount of Carbs as Other Candies

CFSAN issued a Warning Letter on January 22, 2004, to Russell Stover Candies, Inc., Kansas City, Missouri. FDA determined that the labels for Russell Stove® LOW CARB Mint Patties, LOW CARB Toffee Squares, and LOW CARB Pecan Delights caused the products to be misbranded under section 403(a)(1) of the Act (21 U.S.C. 343(a)(1)) because their labels were false or misleading.

The labels each bore the claim "LOW CARB" (meaning low in carbohydrate). A comparison of the carbohydrate content of the products to comparable products, based upon the reference amount customarily consumed of 40 grams (21 CFR 101.12(b)) for these types of products, revealed that they contained the same or similar amounts of carbohydrate. These products were not lower in carbohydrate than other comparable commercial products.

Warning Letter Issued to Firm for Stevia Products

FDA's Los Angeles District Office issued a Warning Letter on September 30, 2004, to United American Industries, Mesa, Arizona. FDA's review of labels for "Wisdom Herbs Sweet Leaf -Stevia Extract," "Wisdom Herbs-Stevia Herbal Tea," and "Wisdom Herbs-Stevia Concentrate" found that the products were represented for use in conventional foods. The Warning Letter stated that the products were adulterated under section 402(a)(2)(C) of the Act, because they contained an unsafe food additive, namely stevia.

Canned Foods

Warning Letter Issued for LACF Violations

FDA's Atlanta District Office issued a Warning Letter on November 18, 2003, to Palmetto Food Packaging, LLC, Greenville, South Carolina. An FDA inspection on August 4-15, 2003, found serious deviations from the low-acid canned foods (LACF) regulations (21 CFR 108 and 113). Failure to comply with all the requirements of 21 CFR 108.35 and the mandatory portions of Part 113 constitutes a basis for the immediate application of the emergency permit control provisions of section 404 of the Act. Such failure renders the low-acid canned foods adulterated under section 402(a)(4) of the Act (21 U.S.C. 342(a)(4)).

The deviations of concern include the following:

1. The firm failed to determine and record the initial temperature of the contents of the containers (pouches) to be processed to ensure the temperature was not lower than the minimum initial temperature stated in the scheduled process (21 CFR 113.83(c)). The firm had not measured and/or recorded the initial temperature for any of the batches of boiled peanuts processed since the firm began operations; and

2. The firm had not conducted, and maintained records of, any visual and/or destructive seam integrity examinations to assure a consistently reliable hermetic seal on the product pouches (21 CFR 113.60(a)(3)). These examinations and tests must be carried out by qualified personnel at intervals of sufficient frequency to ensure proper closing machine performance.

Caterers

Warning Letter Issued to Facility Classified as "Provisional"

Violations of GMPs for Manufacturing, Packing or Holding Human Food Lead to Warning Letter

FDA's New York District Office issued a Warning Letter on July 20, 2004, to Love and Quiches, Ltd., Freeport, New York. An FDA inspection on May 6 and 10, 2004, revealed violations of good manufacturing practice (GMP) regulations in manufacturing, packing, or holding human food (21 CFR 110), and violations of section 361 of the Public Health Service Act and the Interstate Conveyance Sanitation regulations (21 CFR 1250).

The deficiencies of concern include the following:

- Failure to provide a device that would prevent backflow from or cross-contamination between piping systems, as required by 21 CFR 110.37(b)(5) and 1250.30(d). The inspection specifically revealed that the facility did not have a backflow prevention device on the main water line and on the Straham hoses in the pots and pans washing area and dishwashing area; and

- Failure to provide adequate, convenient hand-washing facilities with running water at a suitable temperature, as required by 21 CFR 110.37(e) and 1250.38.

Based on the inspectional findings, FDA classified the facility as "Provisional" for interstate carrier use for a period of thirty days.

Warning Letter to Rail Service Support Facility for Violations of the Public Health Service Act

FDA's Cincinnati District issued a Warning Letter to CSX Transportation, Jacksonville, Florida on 4/16/2004. The District conducted an inspection of the firm's rail service support facility on located in Russell, Kentucky on January 13-14, 2004. The inspection found significant violations of regulations for the Control of Communicable Diseases and Interstate

Conveyance Sanitation, set forth in Title 21, Code of Federal Regulations (CFR), Parts 1240 and 1250, as promulgated under the authority of the Public Health Service (PHS) Act.

Warning Letter to Aircraft Support Facility for Violations of the Public Health Service Act

FDA's Cincinnati District issued a Warning Letter to Regional Airport Authority, Louisville, Kentucky on 3/15/2004. The District conducted an inspection of the firm's aircraft service support facility on 12/1-2/2003. The inspection found significant violations of regulations for the Control of Communicable Diseases and Interstate Conveyance Sanitation, set forth in Title 21, Code of Federal Regulations (CFR), Parts 1240 and 1250, as promulgated under the authority of the Public Health Service (PHS) Act.

Warning Letter to Vessel Food Service Facility for Violations of the Public Health Service Act

FDA's New Jersey District issued a Warning Letter to Horizon Cruises, Weehawken, New Jersey, on 9/17/2004. The District conducted an inspection the firm's vessel food service facility on June 16 and 18, 2004. The inspection found significant violations of regulations for the Control of Communicable Diseases and Interstate Conveyance Sanitation, set forth in Title 21, Code of Federal Regulations (CFR), Parts 1240 and 1250, as promulgated under the authority of the Public Health Service (PHS) Act.

Ceramics

Firm Fails to Hold a Shipment of Ceramics

Target, a store in Minneapolis, Minnesota, failed to hold a shipment of ceramics after being advised that FDA wanted to examine the shipment. After multiple requests for a lot location, Target finally admitted to FDA that they had distributed the entire lot. Upon receiving a Notice of Redelivery from CBP, Target was able to retrieve a small percent of cartons of the

original carton shipment. Liquidated damages were assessed. Target paid the penalty and the case is now closed.

Cosmetics

FDA Alerts Consumers About Adverse Events Associated With "Permanent Makeup"

FDA Receives 50 Complaints Involving Permanent Makeup

On July 2, 2004, FDA issued an alert to the public regarding the number of reported adverse events associated with individuals who underwent certain micropigmentation procedures, a form of tattooing, used to apply "permanent makeup" for lip liner, eyeliner, or eyebrow color. The adverse events were associated with certain ink shades of the Premier Pigment brand of permanent makeup inks, which were manufactured by the American Institute of Intradermal Cosmetics, doing business as Premier Products, Arlington, Texas.

As of July 1, 2004, FDA had been made aware of more than 50 adverse events and investigated additional reports sent to the manufacturer**.** Reactions reported included swelling, cracking, peeling, blistering, and scarring as well as formation of granulomas (chronically inflamed tissue mass associated with an infection) in the areas of the eyes and lips. In some cases, the effects reported caused serious disfigurement, resulting in difficulty in eating and talking.

In July 2003, the manufacturer reported to FDA its intent to remove five of its ink shades from the market, based on six adverse events that had been reported. However, FDA had obtained additional reports of adverse events involving ink shades that were not included in the firm's removal effort. FDA alerted consumers about associated adverse event reports received about Premier Products ink shades identified on CFSAN's website at http://www.cfsan.fda.gov/~dms/cos-tat2.html.

FDA considers intradermal tattoos (including permanent makeup) cosmetics and pigments used in the inks to be color additives requiring premarket approval under the Act. FDA has not traditionally regulated tattoo inks or the pigments used in them. The actual practice of tattooing is regulated by local jurisdictions.

The agency urges consumers and healthcare providers to continue to report adverse reactions from tattoos, including permanent makeup, to FDA, as well as to state and local health

authorities.

Decorative Contact Lenses

Step From the Beach - Decorative Contact Lenses Destroyed

On January 29, 2004, the FDA's Florida District Office took custody of the vials of decorative contact lenses pursuant to a "Stipulation and Hold Harmless Agreement" between the shop selling the lenses, Step From The Beach, Daytona Beach, Florida, and the U.S. Attorney, Orlando, Florida. Except for a few pairs that were retained for educational purposes, the lenses were destroyed. A joint FDA/Florida Department of Health (FLA-DOH) investigation revealed that the firm was routinely selling decorative contact lenses to customers without a prescription, professional fitting or proper care and handling instruction. FLA-DOH immediately issued a Stop Sale Notice for the contact lenses and FDA pursued a seizure action. The seizure recommendation was approved and forwarded to the U.S. Attorney. The "Stipulation and Hold Harmless Agreement" pre-empted the filing and issuance of a Warrant To Seize by the court.

Warning Letter to Beauty Supply Firm

In May 2004, FDA's Baltimore District issued a Warning Letter to Beauty Supply, d/b/a Beauty World, District Heights, Maryland. An FDA inspection found that the firm sold decorative contact lenses without the involvement of a qualified eye care professional, causing the lenses to be adulterated under section 601(a) of the Act. The lenses were also misbranded cosmetics under section 602(a), because the labeling failed to reveal material facts regarding the consequences that may resulted from labeled, customary, or usual conditions of use.

Dairy Products

Warning Letter Issued to Facility for Misbranded Cheese

Monterey Jack Cheese Substituted for Brick Cheese

FDA's Minneapolis District Office issued a Warning Letter on November 26, 2003, to Lemke Cheese and Packaging

Co., Inc., Wausau, Wisconsin. An FDA inspection on July 7-8, 2003, showed that a sample of "FANCY SHREDDED COLBY CHEESE & BRICK CHEESE BLEND," was produced by shredding and blending Cheddar Cheese and Monterey Jack Cheese.

The Cheddar and Monterey Jack Cheese blend was misbranded under section 403(b) of the Act (21 U.S.C. 343 (b)), because it was offered for sale under the name of another food, namely Colby Cheese & Brick Cheese Blend. The product was further misbranded under section 403(g) of the Act (21 U.S.C. 343(g)), because the label represented the product as a blend of Brick Cheese and Colby Cheese, which were subject to the standards of identity established under 21 CFR 133.108 and 133.118, respectively.

Dietary Supplements

Voluntary Destruction: Royal Tongan Limu

In October 2003, FDA witnessed the voluntary destruction of Royal Tongan Limu, a liquid dietary supplement distributed by NBTY, Inc., in Murphysboro, Illinois. This destruction concluded a series of Agency actions that started with the issuance of a Cyber Letter to Dynamic Essentials, Lake Mary, Florida, for health claims associated with the product and which were made on the firm's website. Subsequent follow up revealed that Dynamic Essentials was a subsidiary of NBTY, and that the product was being distributed from NBTY's Illinois location. Even after the issuance of the Cyber Letter, the product remained in distribution channels. FDA was considering a seizure action; however, the firm chose to voluntarily destroy its inventory of bottles of Royal Tongan Limu, along with the product's related literature and materials.

Letters to Firms Marketing Ephedra

FDA Advises Firms of the Agency's Intent to Publish Final Rule Regarding Ephedra

On December 30, 2003, FDA issued letters to approximately 60 firms marketing ephedra. The letter advised the firms that FDA intended to publish a rule in the coming weeks that dietary supplements containing ephedrine alkaloids present an unreasonable risk of illness or injury under conditions of use

recommended or suggested in the labeling of the product, or, if no conditions of use were suggested in the labeling, under ordinary conditions of use, and were therefore adulterated under Section 402(f)(1)(A) of the Federal Food, Drug and Cosmetic Act (the Act).

Coral Calcium Consent Decree of Condemnation and Permanent Injunction

On December 17, 2003, the U.S. District Court for the Northern District of Illinois entered a Consent Decree of Condemnation and Permanent Injunction against Shop America. The decree prohibited "Shop America and each of its directors, officers, agents, representatives, and any and all persons in active concert from directly or indirectly doing or causing any promoting, representing, or suggesting that an article manufactured, marketed, or distributed by Shop America, is safe or effective in the diagnosis or treatment of cancer, multiple sclerosis, lupus, heart disease, high blood pressure, or any other disease in man or other animals." In June 2003, the U.S. Marshals Service, at the request of FDA, seized Coral Calcium Supreme, marketed by Shop America, because of claims made in the labeling of the product.

Judgment: Wildflower Pharmacal, Uttam Sethi

Wildflower Pharmacal (now Aulistic Vitamins Corp.) and Uttam Sethi were convicted of three felony counts relating to their manufacturing of dietary supplements that did not contain the labeled amounts of numerous nutrients. Judgment was filed in EDNY on December 17, 2003. Mr. Sethi received 5 years probation, $ 3 million fine and $1.5 million forfeiture. Wildflower Pharmacal received a $2.4 million fine.

Consumer Advisory and Warning Letter:
FDA Warns Consumers Not to Feed Infants
"Better than Formula Ultra Infant Immune Booster 117"

On January 23, 2004, the Food and Drug Administration issued a warning to consumers that a product, Better Than Formula Ultra Infant Immune Booster 117, sold over the internet as a dietary supplement, should not be fed to infants. Even though NSP Research Nutrition

labeled their product as a dietary supplement, the product appeared to be represented as an infant formula in the product labeling.

On January 30, 2004, FDA issued a Warning Letter to the firm, advising the firm that they had not filed the necessary documentation for a new infant formula. The letter also advised the firm that the product was misbranded, in that it was labeled as a dietary supplement, but did not meet the statutory requirements to be one.

Seizure at Musclemaster.com

On February 5, 2004, the U.S. Marshals Service, at the request of FDA, seized bottles of ephedra-containing dietary supplements Betatrim, Thermbuterol, and Stacker 2, from Musclemaster.com in Northborough, Massachusetts. The complaint alleged that Musclemaster.com was making unsubstantiated claims on its websites for the ephedra-containing products. Specifically, it is alleged that Musclemaster.com claimed that its products enhanced the athletic and muscle performance of consumers without adequate scientific basis to support such claims.

Under the Federal Food, Drug and Cosmetic Act, products labeled as dietary supplements can make structure and function claims, but they cannot make such claims without adequate scientific evidence substantiating the claims. The labeling of dietary supplements must be truthful and not misleading. There is an inadequate scientific basis for claims of enhanced athletic performance for ephedra-containing dietary supplements. FDA filed a Motion for Default Judgment, and, in June 2004, the court entered an order of forfeiture.

Consent Decree Letter Issued: Vital Health

A letter was issued on February 19, 2004, to Vital Health, West Allis, Wisconsin, advising the firm that they were in violation of the court judgment filed against them in 1992. The firm was inspected December 5, 2002, and again on August 7, 2003. During these inspections and by undercover purchase, information was obtained which showed the firm was actively promoting the sale of Herp-Eeze and TobacOff, products labeled as dietary supplements, but which labeling included drug claims.

Consumer Warning: Green Hornet, Promoted as Herbal Version of "Ecstasy"

On February 25, 2004, FDA warned consumers not to purchase or consume a liquid product called Green Hornet. This product is promoted on the Internet, and sold in stores, as a herbal version of the illegal street drug "Ecstasy." FDA considers this product to be an unapproved new drug since it contains, among other ingredients, the undeclared active ingredients diphenhydramine and dextromethorphan, found in over-the-counter drugs. FDA recently became aware of reports of adverse events experienced by four teenagers after consuming Green Hornet. The teenagers were rushed to a hospital emergency room suffering from seizures; excessive heart rates; severe body rashes and high blood pressure. FDA investigated whether Green Hornet alone or in combination with other substances caused the severe adverse reactions.

The Green Hornet product involved in this case was sold by Kekio, Inc., Colorado Springs, Colo., doing business as a store called Mind Excursions. The store, which also operates a website, has stopped selling the product.

Consent Decree of Permanent Injunction: SeaSilver USA, Inc., and Americaloe, Inc.

Firms Agree to Stop Manufacturing and Distributing Violative Products Including Seasilver

On March 8, 2004, the U.S. District Court for the Southern District of California signed a Consent Decree of Permanent Injunction agreed to by the U.S. government, SeaSilver USA, Inc., Americaloe, Inc., of Carlsbad, California, and their principals, Bela Berkes and Jason Berkes. In the Consent Decree, the firms and their representatives agreed to stop manufacturing and distributing violative products, including “Seasilver” – a purported cure-all liquid supplement and to destroy the seized products at their expense under the supervision of a Department of Health and Human Services representative within 60 days of posting bond.

This consent decree followed a coordinated effort in June 2003, between the Federal Trade Commission (FTC) and FDA against SeaSilver U.S.A., Inc., and Americaloe, Inc., their owners, and two of the companies' principal distributors. In June 2003, at FDA’s request, U.S. Marshals seized product from locations in California and Ohio. Under a settlement with

the FTC, entered on March 4, 2004, the SeaSilver defendants and the individual distributors agreed to pay $4.5 million in consumer redress.

Conviction: Hadi Ghadour

On March 9, 2004, Hadi M. Ghandour pled guilty to conspiracy to introduce misbranded and unapproved new drugs into interstate commerce, counterfeiting human growth hormone, and conspiracy to distribute a controlled substance. Ghandour owned and operated Genapharm, Inc., a distributor of supplements specifically marketed to athletes to enhance performance.

During investigations, Ghandour and his co-conspirators were found to be selling tiratricol, a Class I hazard. Ghandour and his co-conspirators also sold products to people seeking alternatives to street drugs. Ghandour also sold alternatives to MDMA ("ecstasy"), a schedule I controlled substance. Ghandour also counterfeited the labels for Nutropin AQ, a human growth hormone manufactured by Genentech, Inc., and placed them on vials containing an insulin mixture.

Ghandour was previously convicted of counterfeiting steroids (misdemeanor) in November of 1998. Two of Ghandour's co-conspirators pled guilty in 2003 and received sentences ranging from probation to three years incarceration. Ghandour faces up to 14 years in prison and a $1,000,000 fine.

Androstenedione Warnings

FDA Issues Warning Letters to 23 Companies Marketing Androstenedione

On March 11, 2004, former Health and Human Services Secretary Tommy G. Thompson announced a crackdown on companies that manufacture, market and distribute products containing androstenedione, or, “andro.” These products act like a steroid once metabolized by the body. As a result they can pose similar kinds of health risks as steroids. These products were generally advertised as dietary supplements that enhance athletic performance based on their claimed anabolic and androgenic properties to stimulate muscle growth and increase production of testosterone.

As part of the crackdown, FDA issued Warning Letters to 23 companies asking them to cease distributing products sold as dietary supplements that contain androstenedione. The Warning Letters notified the firms that they could face enforcement actions if they do not take appropriate actions. Each of the Warning Letters stated that FDA assumes that the firm has a basis to conclude that androstenedione is a dietary ingredient. If androstenedione is a dietary ingredient, FDA believes that it is also a new dietary ingredient for which a premarket safety notification is required. Because no such notification had been submitted, these products were adulterated and their marketing prohibited under the Federal Food, Drug and Cosmetic Act.

Dietary Supplements Promoted Online for Weight Loss

FDA Issues 16 Warning Letters to Dietary Supplement Distributors for Making False Claims Regarding Weight Loss

On March 26, 2004, FDA sent Warning Letters to 16 dietary supplement distributors making false or misleading claims for weight loss products promoted over the internet. Many of these products claim to block starch, carbohydrates and fat calories, while allowing consumers to lose weight without any changes in lifestyle. For example, some of the product labels have claimed:

- "Eat All You Want! Block the Starch and Lose Weight!"
- "Neutralize up to 66 percent of the starch consumed in a meal"
- "This advanced dietary-fat inhibitor helps block the absorption of fat calories"
- "Take 3 capsules before bedtime. Watch the fat disappear!"
- "Guaranteed to block the breakdown of carbohydrates and simple sugars from being converted into fat."

The Warning Letters advised the firms that the unsubstantiated claims caused the products to be misbranded under sections 403(a)(1) and 403(r)(6)(B) of the Federal Food, Drug and Cosmetic Act.

Consumer Warning: "Green Hornet" and Other Products By Cytotec Solutions, Inc.

On April 9, 2004, FDA issued a Press Release warning consumers not to purchase or consume products that claim to provide "safe legal highs" or that were marketed as "street drug alternatives" by Cytotec Solutions, Inc., of Tampa, Florida. The April 9th warning expanded on the February 2004 warning concerning a product called Green Hornet, also marketed by Cytotec Solutions. Products by this company have been promoted and sold on the Internet and in stores as legal versions of illicit street drugs.

In February 2004, FDA issued a warning about adverse events experienced by four teenagers after they consumed Green Hornet Liquid that contained high levels of the over-the-counter drugs diphenhydramine and dextromethorphan. FDA conducted analyses of additional products, manufactured or distributed by Cytotec Solutions, Inc. The analyses found not only the drugs, diphenhydramine HCl and dextromethorphan, but ephedrine and the controlled substances GBL and GHB as well. This firm is no longer producing these products and FDA is working to identify and address additional distributors of the products.

The products included in this warning were Trip2Night, Invigorate II, Snuffadelic, Liquid Speed, Solar Water, Orange Butterfly, Schoomz and Green Hornet Liquid. The labeling for these products listed a variety of herbal and other ingredients but did not indicate either the name of the manufacturer or the presence of these drug ingredients.

Guilty Plea – David Hinkson

David Hinkson, the owner of Water Oz, pled guilty to two FDA-related counts. The firm manufacturers and distributes water-based products, labeled as dietary supplements, and ozone generators and body suits, for which the firm makes claims that they treat a variety of conditions such as AIDS and cancer. In his plea, Hinkson admitted not labeling his lithium water as a drug, despite making drug claims for the product, not labeling the ozone generators as medical devices, and not having approval for marketing the devices as such.

FDA Final Rule on Ephedra Becomes Effective

FDA Issues Final Rule Prohibiting Sale of Dietary Supplements Containing Ephedrine Alkaloids

On February 11, 2004, FDA published a regulation declaring dietary supplements containing ephedrine alkaloids (ephedra) adulterated, because such supplements present an unreasonable risk of illness or injury. The regulation went into effect on April 12, 2004. The final rule prohibits the

sale of products labeled as dietary supplements that contain ephedra.

FDA determined that dietary supplements containing ephedra present an unreasonable risk of illness or injury under conditions of use recommended or suggested in the labeling of the product**,** or, if no conditions of use were suggested in the labeling, under ordinary conditions of use. Prior to banning dietary supplements containing ephedra, FDA had received approximately 2,200 Adverse Event Reports submitted directly to the Agency. In addition, FDA was provided with approximately 16,000 reports from call records submitted by one of the largest distributors of dietary supplements containing ephedrine alkaloids.
Ephedra, also called Ma huang, is a plant whose principal active ingredient is ephedrine, which when chemically synthesized is regulated as a drug. In recent years ephedra dietary supplement products have been extensively promoted to aid weight loss, enhance sports performance, and increase energy.

NVE, Inc. v. DHHS, (D.N.J.). In opposition to the new rule, two manufacturers asked the United States District Court in New Jersey to enter a temporary injunction prohibiting FDA from enforcing the rule. The court ruled that plaintiffs had failed to meet their burden to demonstrate the four elements needed for a Temporary Restraining Order (TRO). In particular, the court found that plaintiffs' late request for a TRO (less than two weeks before the effective date) prevented the court from determining whether plaintiffs were likely to prevail on the merits of their claims, a showing that was critical to meet their burden. The court also ruled for the government on the other three prongs of the TRO standard finding that: (a) plaintiffs failed to show that they would suffer immediate irreparable harm absent a TRO; (b) a TRO would present substantial harm to FDA; and (c) the public interest weighed strongly in favor of denying the TRO. The rule remains in effect while the parties submit additional briefs on the merits of plaintiffs' claims.

On August 4, 2004, U.S. District Judge Joel Pisano issued an Opinion and Order on the proper standard of review to be applied in this challenge to the validity of FDA's Ephedra Final Rule, which declares dietary supplements containing ephedrine alkaloids to be adulterated. NVE, a manufacturer of such dietary supplements, claims that in promulgating the Ephedra Final Rule, which went into effect on April 12, 2004, FDA violated the Dietary Supplement Health and Education Act of 1994 (DSHEA), the Administrative Procedure Act (APA), and the U.S. Constitution.

NVE disagreed with the government over the standard of review the court should apply. "Record review," provided for by the APA, limits the court's review to the record in front of the Agency when it promulgated the rule. "De novo" review means that evidence not before the Agency may be presented to the court. DSHEA provides that, a court shall, on a "de

novo" basis, decide "any issue" arising under the definition of adulteration for dietary supplements.

FDA Issues Warning Letter for Labeling Violations

FDA Analysis Reveals that Product Contains Only 55% of Amount of Folic Acid Listed on the Label

On May 21, 2004, Seattle District issued a Warning Letter to Scientific Botanicals, Co., Inc. The Warning Letter was issued based on violations of the Federal Food, Drug and Cosmetic Act, (the Act) documented during an FDA inspection of the firm in January and February 2004, and FDA analysis. FDA analysis of Hydroxy Folate found that it contained less than 55% of the amount declared on the label. This caused Hydroxy Folate to be adulterated under Section 402(b)(1) of the Act in that a valuable constituent, Folic Acid, had been in part omitted.

In addition, Hydroxy Folate was also misbranded under Section 403(a)(1) of the Act, because the product labeling was false and misleading in that it stated that it contained 400 mcg Folic Acid per serving when it, in fact, did not. The Warning Letter also noted that Hydroxy Folate, Deglycyrrhizinated Licorice D.G.L., and Quercetin were misbranded in that their labels failed to identify the products using the term “dietary supplement,” or a variation of the term using the name of the dietary ingredient. Furthermore, Hydroxy Folate, Deglycyrrhizinated Licorice D.G.L., Quercetin were misbranded under 403(q)(5)(F) in that their labels failed to bear nutrition labeling.

Cyber Letters Issued to Firms for Therapeutic Claims

In 2000, FDA began issuing "cyber" letters, (letters sent electronically via the Internet), to web sites whose online sales of prescription drugs may be illegal. FDA also issues cyber letters to websites that market products labeled as dietary supplements with drug or unsubstantiated structure/function claims. The letters advise these website operators that they may be engaged in illegal activities and informs them of the laws that govern prescription drug sales. In Fiscal Year 2004, FDA issued approximately 60 “cyber letters.”

Jason Vale Receives 63-Month Prison Sentence for Selling Laetrile as a Cure for Cancer

United States v. Jason Vale, (E.D.N.Y.). On June 18, 2004, U.S. District Court Judge John Gleeson sentenced defendant Jason Vale to 63 months in prison and 3 years of supervised release. Vale, through Christian Bros., had sold Laetrile over the Internet as a cure for cancer, and saturated the public with a massive Internet and "spam" E-mailing marketing campaign which guaranteed persons a cancer free life if they used his products.

Previously, the court entered a preliminary injunction ordering Vale and Christian Bros., during the pendency of the suit, not to directly or indirectly sell, distribute, package, label, or promote Laetrile, also known as amygdalin, "Vitamin B-17," or apricot pits. In November 2000, Judge Gleeson permanently enjoined Vale and Christian Bros. from selling, distributing, packaging, labeling, or promoting Laetrile.

Defying the court order, Vale set up a shell corporation in Arizona, and continued to ship the product from the basement of his home. For these activities, Vale was found guilty by a federal jury in Brooklyn, New York, on July 21, 2003, of three counts of criminal contempt. The court also found that Vale had committed fraud in his marketing practices. In addition, Vale defrauded the U.S. government by claiming that he qualified for Legal Aid. As a result, Vale was ordered to reimburse the government $31,000 for the costs of his appointed defense attorney.

Metabolife Indicted for Making False Representations to FDA

On July 22, 2004, United States Attorney Carol C. Lam announced that a Grand Jury sitting in the Southern District of California returned an indictment against San Diego-based corporation Metabolife International, Inc., and its founder, Michael J. Ellis. The indictment charged both defendants with making false, fictitious and fraudulent representations to the Food and Drug Administration (“FDA”), and two counts of corruptly endeavoring to influence, obstruct and impede proceedings concerning the regulation of dietary supplements containing ephedra being conducted by the FDA, an agency of the Department of Health and Human Services. Until FDA banned the sale of ephedra in the United States in 2003, Metabolife was one of the largest retailers of dietary supplements in the United States, based largely on sales of its ephedra-based product, Metabolife 356.

Metabolife and Ellis were charged with falsely representing a number of different material facts to the FDA in letters dated April 17, 1998 and February 9, 1999. These representations included false statements by the Defendants that "Metabolife ha[d] never received one notice from a consumer that any serious adverse health event has occurred because of the ingestion of Metabolife 356" and that the company had a "claims-free history."

U.S. District Judge Issues Permanent Injunction Against Lane Labs-USA, Inc.

On July 13, 2004, FDA announced that Judge William G. Bassler of the United States District Court for the District of New Jersey, found that three products sold by Lane Labs-USA, Inc. and its president Andrew J. Lane (the defendants) as dietary supplements and a cosmetic - Benefin, MGN-3 and SkinAnswer - were, in fact, unapproved new drugs under federal law, because they were being marketed as treatments for cancer, HIV, and skin cancer without FDA approval. In addition, Judge Bassler permanently enjoined the defendants from distributing BeneFin, MGN-3, and SkinAnswer unless the products were first either approved for marketing by FDA or distributed pursuant to an Investigational New Drug (IND) application for purposes of conducting a clinical trial. Judge Bassler also ordered the defendants to pay restitution to all purchasers of BeneFin, MGN-3, and SkinAnswer since September 22, 1999.

FDA issued a warning letter to the defendants in September 1997. Nevertheless, the defendants continued promoting BeneFin, MGN-3, and SkinAnswer as treatments for cancer and other diseases through such means as mailings, Internet web sites, and employee statements. BeneFin, produced from shark cartilage, was promoted as a treatment for cancer. SkinAnswer, a glycoalkaloid skin cream, was marketed as a treatment for skin cancer. MGN-3, a rice-bran extract, was promoted as a treatment for cancer and HIV, the virus that causes AIDS.

The government's request for a permanent injunction was based on the defendants' demonstrated unwillingness to comply with the law.

On July 30, after oral argument, Judge Bassler denied Lane Labs' motion to stay the portions of the July 9 Order that require Lane Labs to disclose financial and shipping information to the government and to formulate a plan for paying restitution. The Court reserved decision on whether to issue a stay pending appeal of the paragraph of the July 9 Order that requires the payment of restitution. Judge Bassler concluded that Lane Labs would suffer irreparable harm if it were required to pay restitution to consumers because if the restitution order were later overturned on appeal, Lane Labs would be unable to recover

the payments that had been made. However, Judge Bassler also refused to stay the restitution requirement unless Lane Labs provided adequate security. The Court therefore ordered Lane Labs to disclose to the government and the Court certified financial information, information regarding Lane Labs' ability to obtain a bond or other security, and the proposed amount of a bond, by August 27th. A hearing on the amount of the bond was set for September 10th.

Judge Bassler also rejected Lane Labs' proposed modification of the paragraph requiring destruction of existing inventories of BeneFin, MGN-3, and SkinAnswer in favor of an alternative proposed by the government.

Firms Voluntarily Destroy Inventory of Ephedra

Three Firms Agree to Destroy Remaining Dietary Supplements Containing Ephedra (ephedrine alkalids)

On August 3, 2004, IDS Sports, Oveida, Florida, voluntarily destroyed dietary supplement products containing ephedra (ephedrine alkaloids). An FDA investigator from the Florida District Office witnessed the voluntary destruction in its entirety.

On August 13, 2004, Europa Sports Products, Inc. coordinated with FDA investigators from the Dallas District Office for the voluntary destruction of liquid products containing ephedra (ephedrine alkaloids). The destruction was completed at a landfill. This destruction resulted from an FDA investigation by the Atlanta District Office of the firm Muscleshoppe, Charlotte, North Carolina.

On August 20, 2004, an FDA investigator observed the voluntary destruction of sport drinks containing ephedra (ephedrine alkaloids) located at Europa Sports Products, Inc., Mesquite. Texas.

Warning Letter to Manufacturer of Cortislim

On August 19, 2004, FDA’s Los Angeles District issued a Warning Letter to Window Rock Enterprises. Window Rock markets Cortislim, a product marketed heavily through infomercials for weight loss. The Warning Letter stated that Cortislim was misbranded under sections 403(a)(1) and 403(r)(6)(B), because the product’s labeling includes unsubstantiated structure/function claims. The labeling of a dietary supplement can bear structure/function claims; however, the manufacturer must have substantiation that the claims are truthful and

not misleading.

Cessation Letter to Hillestad Pharmaceuticals

On Sept. 29, 2004, Minneapolis District issued a letter to Hillestad Pharmaceuticals, Woodruff, Wisconsin, advising the firm that they were in violation of the terms of the Consent Decree of Condemnation and Permanent Injunction. In accordance with the terms of the Consent Decree, the letter advised the firm that they must cease distribution of several of their products for which they were making disease claims. The letter also assessed liquidated damages in the amount of $23,000 for violations of the Consent Decree.

Food Storage

Mass Seizure at Reed Creek Milling, L.L.C.

FDA Inspections Find Live and Dead Insects, Larvae, Cats and Dogs Roaming the Area

On February 4, 2004, investigators from FDA's Baltimore District Office accompanied the U.S. Marshals Service in a mass seizure of various foods at Reed Creek Milling, L.L.C., Wyethville, Virginia. FDA initiated this seizure action, because of pervasive insanitary conditions found at this mill. FDA alleged that these conditions caused the food to be adulterated and that the goods produced at the mill should not be allowed into the food supply.

An FDA inspection of Reed Creek Milling, L.L.C., on September 8-10 and 16, 2003, disclosed a widespread and active insect infestation throughout the warehouse. FDA investigators observed live and dead insects, both adult and larvae, that were sieved from raw and finished product and inside finished product containers. The same species of insects were observed on and around product containers and production and storage equipment.

FDA laboratory analysis confirmed the identity of the insects collected by the investigators from multiple points throughout the firm and from in and around the articles. These insects infest food predominantly in storage due to insanitary conditions, rather than environmental or field contamination. They observed broken and open windows and other building defects

that would allow pests to enter the production and storage area. Equipment was stored haphazardly inside and outside the building that could harbor pests and prevent effective cleaning. They observed overgrowth around the building, spilled products throughout the facility, animal feces on several floors, and spider webbing throughout the firm.

The firm responded in a letter dated September 16, 2003. They listed areas that they had or would clean and their intention to correct the observations of FDA investigators. They promised to divert the contaminated food to animal feed.

However, an FDA inspection of the firm on December 9-10, 2003, revealed that the infestation continued. Insects were observed in and around processing equipment on several floors of the firm. Cats and dogs were observed roaming freely throughout the mill. Animal feces were observed on multiple floors of the firm. The firm's owner acknowledged trapping five or six raccoons inside the building since the previous inspection. Building defects such as broken windows and gaps in the walls and ceilings had not been repaired and haphazard equipment storage and spider webbing were also observed.

This infestation is part of a long history of insanitary conditions at the firm. The Virginia Department of Agricultural and Consumer Services (VDACS) inspected the firm on approximately 22 occasions over about 13 years under contract with FDA. Each inspection found some infestation by insects, birds, bats, cats, dogs, or raccoons. However, 11 of those 22 inspections indicated that some action was necessary to correct those infestations. VDACS held an administrative hearing with the firm's management in June 1998 and sent them a letter in August 2002 enumerating violations of Virginia law and warning that further action may be necessary.

FDA's inspection of the mill revealed that the mill operators had failed to provide adequate protection against pest contamination of both the flour and corn processed at the facility. As a result, FDA inspectors found many indications that insects as well as other animals such as cats, dogs and raccoons may have come into direct contact with these food items. Evidence of such pest exposure included animal tracks and feces found in several locations at the mill.

Because of these findings, along with the extremely decrepit condition of the mill, FDA concluded that continued operation of the facility caused the food it processes to be in violation of the law and sought a court order for seizing all food material stored at the mill. Under the terms of the seizure order granted by U.S. District Court for the Western District of Virginia, the seized goods would be held until their final disposition was determined.

Rodent Infestation Results in Seizure at Hung Hua Trading

Widespread Rodent Infestation Results in Seizure

At the request of FDA, U.S. Marshals seized various articles of foods at Hung Hua Trading, Inc., Mount Juliet, Tennessee on August 12, 2004. The seizure action was initiated after FDA found extensive evidence of rodent infestation throughout the firm's warehouse facility and cold storage warehouse area during a recent inspection.

The U.S. Marshal seized all FDA-regulated items susceptible to rodent contamination. The seized products were considered adulterated under the Act, because they were held under insanitary conditions. Hung Hua Trading, Inc., stores and distributes institutional-sized packages of foods and ingredients, including shrimp, kokuho and sweet rice and lo mein noodles, that were typically used in the preparation of foods in restaurants. Hung Hua Trading, Inc. distributed their products in nine states.

U.S. Seizes Contaminated Food Articles at Phoenix Enterprises, Inc.

FDA Inspection Discloses Rodent Nests, Rodent Gnawed Holes and Multiple Dead Rodents

FDA announced that on November 26, 2003, U.S. Marshals seized articles of adulterated food from Phoenix Enterprises, L.L.C., a food distributor and storage warehouse located in Washington, D.C. U.S. Marshals seized scores of containers of food at this facility after a government investigation determined that the articles of food had been subject to widespread and active rodent infestation. The U.S. has also filed a civil Verified Complaint for Forfeiture in rem against the adulterated food articles in the U.S. District Court for the District of Columbia, seeking condemnation of the food articles in accordance with the Act.

The Government's Verified Complaint alleged that an inspection conducted by FDA disclosed widespread and active rodent infestation at Phoenix Enterprises, L.L.C. According to the Verified Complaint, multiple dead rodents, as well as a number of rodent nests, rodent gnaw holes, and hundreds of rodent excreta pellets were observed in storage areas throughout this facility, in, on and around the articles of food. The seized articles of food included food in permeable containers, such as paper, cloth, boxes, cartons and plastic, which were subject to penetration by rodents or their filth.

FDA inspected Phoenix Enterprises, L.L.C. five times since March 2002. Despite the promises and corrections made by the firm, each inspection revealed a continuing widespread

and active rodent infestation that was supported by the poor physical conditions and overcrowding within the facility. Each time, Peter Y. Chan and Gerald T. Chan, owner/operators, received verbal warnings and finally, FDA issued a Warning Letter on March 27, 2003. The letter requested that the violations be corrected and stated that failure to correct the violations may result in regulatory action, including seizure and injunction. The firm did not respond to the Warning Letter.

An FDA inspection conducted on September 15 and 24, 2003, confirmed a continuing widespread and active rodent infestation in the buildings. Therefore, the articles of food at Phoenix Enterprises, L.L.C. continued to be held under insanitary conditions whereby they may have become contaminated with filth.

FDA's laboratory analysis of a number of samples taken during an August 13-September 5, 2003, inspection confirmed gnawed holes in food packaging, and the presence of rodent excreta pellets, urine, and hairs.

Phoenix Enterprises, L.L.C. markets and distributes dried oriental noodles and other miscellaneous dried food products. The following products are examples of some of the products in the warehouse: Tapioca Ball, Nong Shim Chin Cup; Nong Shim Neoguri Udon Seafood; Tapioca Starch; Vifon Pho Bo, An Lien Oriental Style Beef Noodle; Pute Tamarind without Seed; Rock Sugar Yellow Lump; Egret Brand His Nhua Rice Stick; and Peeled Split Mung Bean.

Follow-Up to Seizure at Nuts and Spice Co.

United States v. 45/55 pound bags, more or less, of an article of food, et al., (E.D. Ca.).On March 31, 2003, District Judge Garland E. Burrell, Jr. entered a Stipulation and Final Decree of Condemnation and Destruction in this seizure action. In its Complaint, the U.S. alleged that the defendant articles were adulterated foods in that they were prepared under insanitary conditions whereby they may have been contaminated with filth.

The Decree condemned the articles and required the claimant, Nuts and Spice Co., to destroy them. The Decree also prohibited the claimant from receiving, storing, making, and shipping any additional food, at its facility located in Tracy, California, until the claimant has been advised by FDA that the facility has been made sanitary. This Decree followed a previous decree in a similar action against food owned by Nuts and Spice Co. in which FDA obtained the right to demand that the company immediately discontinue its activities

if FDA finds that any food held at any facility operated by the claimant is adulterated or otherwise in violation of the Act.

Warning Letter Issued to Facility for Adulteration Due to Filth

FDA's San Francisco District Office issued a Warning Letter on March 3, 2004, to Wing Kee Foodstuff Co., San Francisco, California. An FDA inspection on November 4, 5, 6, 7 and 28, 2003, revealed numerous deviations from GMP regulations (21 CFR 110). These conditions caused the products stored in the facility to be adulterated under section 402(a)(4) of the Act, in that they were prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth.

The insanitary conditions observed by FDA's investigator included the following:

1. The firm failed to take effective measures to exclude pests from the storage facility and to protect against the contamination of food on the premises by pests (21 CFR 110.35(c)); and

2. The firm failed to provide sufficient space for storage of materials as is necessary for the maintenance of sanitary operations (21 CFR 110.20(b)(1)).

Fruit

Warning Letter Issued Due to Misbranded Dried Cranberries

FDA's Los Angeles District Office issued a Warning Letter on May 12, 2004, to World Variety Produce, Inc., Vernon, California. FDA analyzed the contents of and reviewed the label for the product Melissa's Dried Cranberries, 3 ounce retail packages. An FDA investigator collected a sample of the dried cranberry product during an inspection at the firm conducted on December 30-31, 2003. FDA analyzed the Vitamin C content and compared the results to the amount declared on the label of the product.

Label On Cranberries States 20% Vitamin C – FDA Analysis Finds 0.06% and 0.26% (Original and Check Analysis)

The product, Melissa's Dried Cranberries, 3 ounce retail package, was misbranded under

section 403(a)(1) of the Act (21 U.S.C. 343(a)(1)) in that the labeling was false or misleading. The label states that the product contains 20% of the daily value of Vitamin C. However, the laboratory analysis found the product to contain 0.06% and 0.206% (original and check analysis, respectively) of the daily reference intake of Vitamin C. A food is deemed to be misbranded under 21 CFR 101.9(g)(4)(ii) if the level of a naturally occurring nutrient in a food is less than 80% of the value for that nutrient declared on the label.

Imports

FDA Import Exam Finds Product Subject to Import Alert for Filth

FDA's Los Angeles District Import Operations performed a physical examination of an entry invoiced and electronically transmitted as cartons of pasta. The examination showed the product to be cartons of rice sticks from a manufacturer in China whose product is subject to Import Alert #02-02 for filth. CBP seized the entire container.

FDA Import Exam Finds Peanuts Declared as Baked Snacks

FDA's Los Angeles District Import Operations performed a physical examination of an entry originating in Thailand, in June 2004. The electronic entry and commercial invoice declared cartons of three different flavored baked snacks. The examination of the container revealed cartons of peanuts, which were subject to treasury quota and which carry a high duty. U.S. Customs and Border Protection (CBP) was notified and they collected the quota duty fees and assessed penalties against the importer for failure to declare the peanuts.

Moldy Fish Results in Liquidated Damages

In August 2004, FDA's Atlanta District Office sampled an entry of African smoked fish which was found violative for excessive viscera and mold by the Southeast Regional Laboratory. After FDA refused admission of the smoked fish, U.S. Customs and Border Protection (CBP) initiated a redelivery request. Follow-up investigation by FDA and CBP disclosed that the importer had taken possession of and distributed the smoked fish. FDA

recommended and CBP assessed a liquidated damage penalty of $1,000 against the importer for failure to redeliver.

Decomposing Salmon

FDA Investigators Find Truck's Refrigeration Not Operating

In July 2004, FDA's Seattle District Office was informed by U.S. Customs and Border Protection (CBP) in Blaine, Washington, of the outcome of a case involving partial distribution of a refused lot of fresh, farm-raised Atlantic salmon. The entry entered the U.S. in a refrigerated truck; however, FDA's Seattle District Office investigators observed that the truck's refrigeration unit was not operating and that the truck's cargo area was at an ambient temperature. The investigators performed a field sensory exam of the product, found odors indicative of decomposition, and collected a sample. The Pacific Regional Laboratory sensory laboratory confirmed the investigators finding of decomposition.

After FDA refused admission, the importer requested for FDA to witness destruction of the refused product. However, when FDA arrived to witness the destruction, it was determined that the importer had distributed approximately half of the shipment. FDA notified CBP and CBP subsequently assessed a $3,409 penalty against the importer of record. CBP closed the case since the importer of record paid the fine.

Bad Merchandise, Even Concealed, Cannot Hide from FDA and CBP

Importers Attempt To Hide Product Subject to Import Alert

This joint investigation between FDA's New York District Upstate, and New York District Downstate and U.S. Customs and Border Protection (CBP) was initiated on August 25, 2000, when a shipment of cases of shrimp arrived at the Port of Newark. The shipment was subject to Import Alert #16-81 and was detained by the New York District Office without physical examination. The private laboratory report submitted by the consignee was positive for Salmonella and the lot was refused admission on October 11, 2000.

The outbound truck containing the refused shrimp was examined by CBP and FDA at the Lewiston Bridge on February 8, 2001. A physical count of the truck's contents revealed cases of shrimp were on the truck and the initial examination of the cartons in the tail of the

truck revealed cases labeled with the refused shipment packer's name. However, an intensive examination of the truck's contents by FDA and CBP uncovered what appeared to be a carefully orchestrated substitution attempt. While cases were labeled with the refused shipment packer's name, examination of the remaining cartons underneath the stick-on carton labels revealed labels identifying different packers, three of which were subject to Import Alert #16-81. The cartons of shrimp under CBP detention since the substitution attempt on February 8, 2002, were seized by CBP.

On April 6, 2004, Rochelle De Grand, pled guilty before the U.S. District Judge, Ronald J. Hedges, to a one-count complaint, which charged the introduction of adulterated food into interstate commerce, in violation of 21 U.S.C. 331(a) and 333(a)(1), and 21 U.S.C. 2.

Medical Foods

Warning Letter Issued for Products Represented as Medical Foods

Claims on Medical Food Cause Products to be Drugs

FDA's Los Angeles District Office issued a Warning Letter on October 1, 2003, to Metagenics, Inc., San Clemente, California. An FDA inspection from May 6-19, 2003, found the labels for UltraClear®, UltraMeal®, UltraInflamX™, and UltraGlycemX™ to cause the products to violate the Act in several respects.

The products were labeled as "medical foods," and were represented on the labels as intended for use with a variety of medical conditions. The products did not meet the definition of a medical food as defined in the Orphan Drug Act Amendments of 1988 (21 USC 360ee (b)(3)) as a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, were established by medical evaluation. The regulations further define a medical food as one that is intended for the dietary management of a patient who has special medically determined nutrient requirements, the dietary management of which cannot be achieved by the modification of the diet alone (21 CFR 101.9(j)(8)(ii)). The products were not medical foods because the diseases and conditions described in the product labels did not have distinct nutritional requirements and because the products did not have any unique

impact on the dietary management of those diseases and conditions beyond that which could be achieved by modification of the normal diet alone.

Because the products did not meet the definition of a medical food, they were not afforded the exemption from nutrition labeling afforded medical foods. Therefore, the products were misbranded under section 403(q)(1) of the Act, because the labels did not bear nutrition labeling in the appropriate format, as prescribed in 21 CFR 101.9. In addition, the products bore label claims suggesting that they were useful in the treatment of various diseases.

Such claims are evidence that the products were intended for use as drugs under section 201(g)(1)(B) of the Act. The products are new drugs under section 201(p) of the Act, because there is no evidence that these products are generally recognized as safe and effective for their intended uses.

Nuts

FDA Issues Alert on Additional Recalled Stocks of Paramount Farms Raw Almonds

***Salmonella* Enteritidis Found In Raw Almonds**

On May 21, 2004, FDA advised distributors, wholesalers and consumers that a recall of raw almonds due to reports of *Salmonella* Enteritidis (SE) that was announced by Paramount Farms, Lost Hills, California, on May 14, 2004, was expanded. Before eating any raw almonds having a "best before" date of August 21, 2004, or later, consumers were advised to check with the store where they purchased the product to see if the almonds came from Paramount Farms.

FDA learned that Paramount Farms distributed the recalled almonds in bulk or packaged nationwide to brokers, distributors and grocery store chains which in turn sold the almonds to consumers in a variety of package sizes with a variety of brand names. The almonds were also distributed to eight other countries.

The almonds had the potential to be contaminated with SE, an organism that can cause serious and sometimes fatal infections in young children, frail or elderly people, and others with weakened immune systems. Healthy persons infected with SE often experience fever, diarrhea (which may be bloody), nausea, vomiting and abdominal pain. In rare

circumstances, infection with SE can result in the organism getting into the bloodstream and producing more severe illnesses such as arterial infections (i.e., infected aneurysms), endocarditis and arthritis. FDA advised consumers who were experiencing symptoms that could be salmonellosis should consult their health care providers or their local health department.

Prepared Foods

Warning Letter Issued Due to Misbranded Fried Rice

Undeclared Wheat – A Known Allergen - Cause Fried Rice to be Misbranded

FDA's Minneapolis District Office issued a Warning Letter on June 28, 2004, to Craigador Corporation, Minnetonka, Minnesota. An FDA inspection on February 24, 2004, and label review revealed that the firm's "Oriental Fried Rice" was misbranded under sections 403(a)(1) and 403(i)(2) of the Act and 21 CFR 101--Food Labeling.

The "Oriental Fried Rice" was misbranded under section 403(i)(2) of the Act in that it was fabricated from two or more ingredients but the label fails to bear the common or usual name of each ingredient in the product (21 CFR 101.4). The label for the oyster sauce showed numerous ingredients not included on the "Oriental Fried Rice" label, including wheat flour and monosodium glutamate (MSG).

The letter advised the firm that wheat is a known allergen. Undeclared ingredients that are known allergens are of particular concern to the agency. FDA received an increasing number of reports concerning consumers who have experienced adverse reactions following exposure to an allergenic substance in foods. For sensitive individuals, the presence of allergens in food is potentially life threatening. Ingredients that are among the most commonly known to cause serious allergic responses are milk, eggs, fish, crustaceans, tree nuts, wheat, peanuts, soybeans, and derivatives of these products. The label stated "NO MSG." Oyster sauce was an ingredient of the oriental fried rice and its label identified that this sauce did contain MSG. This caused the "Oriental Fried Rice" to be misbranded under section 403(a)(1) because the labeling was false and misleading.

Seafood

Warning Letter Issued for Deviations from HACCP Regulations

FDA's New England District Office issued a Warning Letter on July 16, 2004, to Stonington Sea Products, Inc., Stonington, Maine. An FDA inspection on April 6-7, and 13, 2004, confirmed the presence of *Listeria monocytogenes* in a lot of ready-to-eat (RTE) cold-smoked, vacuum-packed Atlantic salmon, which caused the lot of seafood to be adulterated under section 402(a)(1) of the Act, 21 U.S.C. 342(a)(1), in that the product contained a poisonous or deleterious substance which may have rendered it injurious to health.

FDA found serious deviations from the seafood HACCP regulation, 21 CFR 123. In accordance with 21 CFR 123.6(g), failure of a processor to have and implement a HACCP plan that complies with this section, or otherwise operate in accordance with the requirements of this part, renders the fishery products adulterated under section 402(a)(4) of the Act, 21 U.S.C. 342(a)(4). Accordingly, the RTE cold-smoked, vacuum packed Atlantic salmon products were adulterated in that the products had been prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth, or whereby they may have been rendered injurious to health.

Crabmeat Containing Chloramphenicol is Seized at Southern Cold Storage Company

On July 2, 2004, at the request of FDA, U.S. Marshals seized approximately cases of Bernard's brand frozen crabmeat, while it was being held for sale at Southern Cold Storage Company, Baton Rouge, Louisiana. The crabmeat was seized because it was adulterated with an unapproved food additive, Chloramphenicol (CAP).

The U.S. Marshals seized cases of pasteurized special white crabmeat; cases of pasteurized special claw crabmeat; and cases pasteurized jumbo lump crabmeat.

CAP is a broad-spectrum antibiotic drug used to treat life-threatening infections in humans, usually when other alternatives are not available. The use of this antibiotic is limited because

of its potentially life-threatening side effect, idiosyncratic aplastic anemia. For the very small number of the population susceptible to this side effect, exposure to CAP could be serious or life threatening. Because of the current uncertainty regarding the dose-response relationship between CAP ingestion and aplastic anemia, it is not possible to define a safe level for the presence of this antibiotic in food products.

In June 2002, FDA announced increased sampling of imported seafood for the presence of CAP. This action was taken because some states and other countries detected low levels of CAP in imported shrimp and crayfish.

Dried Whole Sea Cucumbers Seized at Hoo Come Corporation

FDA's Los Angeles District investigators accompanied the U.S. Marshals Service in a seizure of various types of dried and vacuum packed frozen seafood products, including whole sea cucumbers at Hoo Come Corporation, located in City of Industry, California. The seizure occurred on October 4, 2004. The products at Hoo Come Corporation were imported from Hong Kong and other foreign sources. FDA examination of the sea cucumbers revealed that the product consisted in part of a filthy substance because it was heavily infested with live and dead insects, insect larvae, and other insect filth. In addition, the product had been held under insantary conditions whereby it may have become contaminated with filth.

Florida Crab Company, Inc., Enjoined

United States v. Florida Crab Company, Inc., (N.D. Fla.). On June 29, 2004, U.S. District Court Judge Robert L. Hinkle entered a Default Judgment and Order of Permanent Injunction in this case. After receiving notice of the government's intent to file suit, the defendants represented that they had permanently ceased all operations but refused to agree to injunctive provisions applicable to any future crab processing, so the government filed its Complaint on December 11, 2003. The defendants refused to negotiate, did not file an answer, and represented that they would take no action regarding the case. The government filed a motion for entry of default judgment and permanent injunction, which was promptly granted by the court. The Order permanently enjoined the defendants from receiving, preparing, packing, and distributing any crabmeat products or live raw crabs unless and until they had taken specific steps to ensure that their operations are in compliance with the Act, applicable regulations, and the court's Order.

FDA Obtains Injunction Against Ocean Fresh Crab Company

On April 23, 2004, Ocean Fresh Crab Company signed a consent decree of permanent injunction against the processing, preparing, packing, holding and distributing of any ready-to-eat crabmeat products (including jumbo lump, lump, claw, and cocktail claw fingers) processed by Ocean Fresh Crab Company under insanitary conditions. The firm was formerly known as Barwick's Ocean Fresh Crab Company, 1616 Coastal Highway, Hwy 98, Panacea, Florida.

The government's complaint, filed by the U.S. Department of Justice in the U.S. District Court for the Northern District of Florida, charged the defendant Norman Barwick, with violating the Food, Drug and Cosmetic Act by causing the introduction into interstate commerce of ready-to-eat crabmeat products that were adulterated within the meaning of 21 U.S.C. § 342(a)(4).

The complaint asserted that the defendant violated 21 U.S.C. § 331(a) by causing articles of food, namely ready-to-eat crabmeat products, to become adulterated during processing since 1999, despite FDA's warnings that these actions were illegal.

These violative actions posed a public health hazard because ready-to-eat crabmeat products processed under insanitary conditions have been shown to be the source of *Escherichia coli* (E. coli), *Salmonella, Staphylococcus aureus, Listeria monocytogenes*, and other pathogenic microorganisms which have caused foodborne illness outbreaks. Humans who consume food containing pathogenic bacteria can suffer adverse health consequences, depending on the type and amount of contamination, including severe gastroenteritis, miscarriage or stillbirth, and even death. The risk to the public is even higher for ready-to-eat crabmeat that is processed under insanitary conditions because it may be eaten without further heating or cooking by the consumer.

Barwick Crab Company Signs Consent Decree of Permanent Injunction

On March 11, 2004, Barwick Crab Company signed a consent decree of permanent injunction against the processing, preparing, packing, holding and distributing of any ready-to-eat crabmeat products (including fresh jumbo lump, lump, claw, and cocktail claw fingers) processed by Barwick Crab Company, 38 Barber Road, Crawfordville, Florida, under

insanitary conditions. There is currently no product in the marketplace.

These violative actions posed a public health hazard because ready-to-eat crabmeat products processed under insanitary conditions have been shown to be the source of *Escherichia coli* (E. coli), *Salmonella, Staphylococcus aureus, Listeria monocytogenes,* and other pathogenic microorganisms which have caused food borne illness outbreaks. Humans who consume food containing pathogenic bacteria can suffer adverse health consequences, depending on the type and amount of contamination, including severe gastroenteritis, miscarriage or stillbirth, and even death. The risk to the public is even higher for ready-to-eat crabmeat that is processed under insanitary conditions because it may be eaten without further heating or cooking by the consumer.

The government's complaint, filed by the U.S. Department of Justice in the U.S. District Court for the Northern District of Florida, charged the defendants, Elise F. Barwick and Charles Ferrell Barwick, with violating the Food, Drug and Cosmetic Act by causing the introduction into interstate commerce of ready-to-eat crabmeat products that were adulterated within the meaning of 21 U.S.C. § 342(a)(4).

The complaint asserted that the defendants violated 21 U.S.C. § 331(a) and 21 U.S.C. § 331(k) by causing articles of food, namely ready-to-eat crabmeat products and live crabs, to become adulterated during processing since 1998, despite FDA's warnings that these actions were illegal.

Spices

FDA Issued Alert on Foodborne Illness Associated with Certain Basil and Mesculin/Spring Mix Salad Products

On May 21, 2004, FDA issued an alert to consumers that two outbreak clusters of a gastrointestinal illness known as cyclosporiasis may be associated with raw basil and mesculin/spring mix salad served in Texas and Illinois. The agency worked with the Centers for Disease Control and Prevention (CDC) and state and other health authorities to determine the cause and scope of the problem.

Cyclosporiasis is caused by the ingestion of the Cyclospora parasite and results in the infection of the small intestine. It causes watery diarrhea with frequent, sometimes explosive, bowel movements. Other symptoms include loss of appetite, substantial weight loss, stomach cramps, nausea, vomiting, muscle aches, low-grade fever and fatigue. Symptoms usually

develop about a week after consuming the contaminated food. Cyclospora infection can be successfully treated with appropriate antibiotic therapy. Individuals experiencing these symptoms after consuming basil and mesculin/spring mix salad products were advised to consult their physicians and notify their local health departments.

The two outbreak clusters to date were:

- In February 2004, approximately 57 individuals in Wheaton, Illinois, were reported sick after consuming food containing basil and mesculin prepared by a restaurant. Twenty of these cases were confirmed by laboratory testing to have been stricken with cyclosporiasis.

- In that same month 38 people in Irving, Texas, were also reported ill after eating basil and mesculin mix at a local restaurant. Sixteen of these cases were later confirmed by laboratory testing as cyclosporiasis.

Warning Letter Issued for Adulterated Red Pepper Powder

FDA's Los Angeles District Office issued a Warning Letter on November 13, 2003, to Golden Luck Inc., Commerce, California. FDA detained an import shipment of red pepper powder pursuant to sections 402(a)(1) and 801(a)(3) of the Act, 21 U.S.C. 342(a)(1) and 381(a)(3). FDA sampled the red pepper powder and found Salmonella, a poisonous and deleterious substance which caused the product to be adulterated under section 402(a)(1) of the Act, 21 U.S.C. 342(a)(1).

On August 11, 2003 the firm initiated a voluntary recall of this red pepper powder shipment because it had been sold and distributed into U.S. commerce. The firm was able to recall and destroy, under FDA supervision, returned bottles and sold bottles on August 26, 2003.

In addition, on September 4, 2003, the firm submitted to FDA standard operating procedures for handling FDA regulated commodities which outlined the firm's intent to follow a procedure for holding merchandise under FDA hold/detention pending an FDA release.

Vegetables

Sprouters Northwest, Inc. Recalls Raw Alfalfa Sprouts Due to Possible Health Risk

On June 3, 2004, FDA was alerted that Sprouters Northwest, Inc., Kent, Washington was recalling 2, 3, and 5 pound institutional trays of its raw alfalfa sprouts. The sprouts, which had been sent to various food institutions, were being recalled because they were possibly linked to a recent increase in Salmonellosis in Oregon and Washington State.

As of June 3, 12 cases of *Salmonella* Bovismorbificans possibly linked to the consumption of raw alfalfa sprouts were reported. In light of these outbreaks, FDA reiterated its previous alerts about eating raw sprouts. Those persons who wished to reduce the risk of foodborne illness from sprouts were advised not to eat raw sprouts. This advice is particularly important for children, the elderly, and persons with weakened immune systems, all of whom are at high risk of developing serious illness due to foodborne disease. People in high-risk categories should not eat raw sprouts.

Salmonella Bovismorbificans is an organism rarely seen in the U.S. It can cause serious and sometimes fatal infections in young children, frail or elderly people and others with weakened immune systems. Healthy persons infected with Salmonella often experience fever, diarrhea (which may be bloody), nausea, vomiting and abdominal pain. In rare circumstances, infection with Salmonella can result in the organism getting into the bloodstream and producing more severe illnesses such as arterial infections (i.e., infected aneurysms), endocarditis (swelling of the lining the heart) and arthritis. Most cases were resolved without the need for medical attention.

FDA Update on Recent Hepatitis A Outbreaks Associated With Green Onions From Mexico

On December 9, 2003, FDA reaffirmed that several recent Hepatitis A virus outbreaks were associated with eating raw or undercooked green onions (scallions). Investigations by state and local health departments, Centers for Disease Control and Prevention (CDC) and FDA determined that the outbreaks were caused by green onions traced to Mexico for the three outbreaks with completed traceback investigations.

Hepatitis A virus is transmitted by fecal-oral route. Produce can become contaminated when a person who has Hepatitis A or whose hands are contaminated with Hepatitis A virus comes

into contact with the product or by exposure of the product to water contaminated with Hepatitis A virus.

Hepatitis A outbreaks associated with raw or undercooked green onions served in restaurants occurred in Tennessee, North Carolina and Georgia in September 2003, and in Pennsylvania in late October through early November 2003. The source of the green onions in the outbreaks was traced to Mexico for the Tennessee, Georgia and Pennsylvania outbreaks. The source of the onions in the North Carolina outbreak was not determined. The exact source of the contamination has not been established in any of these outbreaks.

A team of investigators from FDA and CDC spent the first week of December 2003, in Mexico working with Mexican officials and visiting the four firms and associated facilities identified in the FDA traceback investigations.

FDA and the Mexican government are working together on an ongoing basis with regard to technical issues arising from the process of investigating all possible sources of implicated products in foodborne outbreaks. FDA and Mexican health and agriculture authorities are engaged in a joint effort to ensure the safety of Mexican produce entering the U.S. and improving the health of citizens on both sides of the border.

Hepatitis A is a liver disease that develops within 2-6 weeks after exposure. Hepatitis A is usually mild and characterized by jaundice (yellow discoloration of the skin), fatigue, abdominal pain, loss of appetite, nausea, diarrhea, and fever. It can occasionally be severe, especially in people with liver disease. Persons infected with Hepatitis A virus, in particular children, may have no symptoms or very mild symptoms.

Certain Roma Tomatoes as Source of Foodborne Illness Outbreaks in Pennsylvania, Ohio, and Mid-Atlantic States

On July 23, 2004, FDA announced that the agency was working closely with CDC and several state health and agricultural agencies. Both agencies were focusing on certain pre-sliced tomatoes as the likely source of Salmonellosis in Pennsylvania, Ohio, Maryland, Virginia, and West Virginia.

Since July 2, 2004, 289 cases of Salmonella were reported in these states. Many appeared to be related to pre-sliced Roma tomatoes purchased at deli counters in gas stations between July 2-9, based on an epidemiological investigation of the Salmonella cases.

Vessel Watering Points

Warning Letter Issued for Vessel Watering Points

FDA's New York District Office issued a Warning Letter on June 29, 2004, to Canadian American Transportation Systems, Rochester, New York. An FDA inspection on June 8, 2004, revealed that the facility failed to provide adequate backflow prevention devices, failed to properly identify potable and non-potable hydrants on the same pier, and failed to ensure water hoses were of acceptable material and condition.

Based on the inspectional findings, FDA classified the facility as "Provisional" for interstate carrier use due to the serious deviations from the interstate conveyance sanitation regulation (21 CFR Part 1240) promulgated under the Public Health Service Act..

Warning Letters for Deviations from the Public Health Service Act

- FDA's New England District Office issued a Warning Letter on June 17, 2004 to the Massachusetts Port Authority, East Boston, Massachusetts. An FDA inspection on April 28-29, 2004 and May 5, 2004 determined that the Black Falcon Cruise Terminal failed to equip their vessel potable watering points with backflow prevention devices. The firm's watering points were placed on "Provisional" status due to the serious deviation from the interstate conveyance sanitation regulation (21 CFR Part 1240) promulgated under the Public Health Service Act.

- FDA's Cincinnati District issued a Warning Letter to Comair, Inc., on March 3, 2004. The District conducted an inspection on December 5, 2003. The inspection noted critical deficiencies at the watering point and service area operated by the firm. The inspection found significant violations of regulations for the Control of Communicable Diseases and Interstate Conveyance Sanitation, 21 CFR, Parts 1240 and 1250, as promulgated under the authority of the Public Health Service Act.